4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0150]

Revocation of Two Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute (Cleveland Clinic) for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorizations for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR are revoked as of October 19, 2022.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 3, 2020, FDA issued an EUA to Cleveland Clinic for the Cleveland Clinic SARS-CoV-2 Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On August 9, 2021, FDA issued an EUA to Cleveland Clinic for the SelfCheck COVID-19 TaqPath Multiplex PCR, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on October 28, 2021 (86 FR 59738), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

In a request received by FDA on October 7, 2022, Cleveland Clinic requested revocation of, and on October 19, 2022, FDA revoked, the Authorization for the Cleveland Clinic SARS-CoV-2 Assay. Because Cleveland Clinic notified FDA that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future and requested FDA revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on October 7, 2022, Cleveland Clinic requested revocation of, and on October 19, 2022, FDA revoked, the Authorization for the SelfCheck COVID-19 TaqPath Multiplex PCR. Because Cleveland Clinic notified FDA that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR and does not plan to use it in the future and requested FDA revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at https://www.regulations.gov/.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs of Cleveland Clinic for the Cleveland Clinic SARS-CoV-2 Assay and SelfCheck COVID-19 TaqPath Multiplex PCR. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

October 19, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
Re: Revocation of EUA200313

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay issued on August 3, 2020, and amended on January 19, 2021, and September 23, 2021. Cleveland Clinic indicated that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cleveland Clinic has notified FDA that it is no longer using the Cleveland Clinic SARS-CoV-2 Assay and does not plan to use it in the future and requested FDA revoke the EUA for the Cleveland Clinic SARS-CoV-2 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200313 for the Cleveland Clinic SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cleveland Clinic SARS-CoV-2 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

October 19, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195
Re: Revocation of EUA210363

Dear Dr. Harrington:

This letter is in response to the request from Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute ("Cleveland Clinic"), received via email on October 7, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay issued on August 9, 2021. Cleveland Clinic indicated that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cleveland Clinic has notified FDA that it is no longer using the SelfCheck COVID-19 TaqPath Multiplex PCR assay and does not plan to use it in the future and requested FDA revoke the EUA for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210363 for the SelfCheck COVID-19 TaqPath Multiplex PCR assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SelfCheck COVID-19 TaqPath Multiplex PCR assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: October 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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